

**DATA SUMMARY AND REVIEW**  
**HONEY BEE - ACUTE CONTACT & ORAL LC<sub>50</sub> TEST**

**USEPA i 141-1 & Nonguideline; OPPTS 850.3020**

<b>Data requirement:</b>	PMRA Data Code	{.....}
	EPA DP Barcode	353315
	OECD Data Point	{.....}
	EPA MRID	47372347
	EPA Guideline	850.3020

**Test material:** AE C656948 (AI: Fluopyram)      Purity: 95.5%

Common name: Fluopyram

Chemical name: IUPAC: Not reported  
CAS name: Not reported  
CAS No.: Not reported  
Synonyms: None provided

**EPA PC Code:** 080302

**Citation:** Schmitzer, S. 2005. Effects of AE C656948 (Acute and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory. Unpublished study performed by IBACON GmbH, Rossdorf, Germany. Laboratory Report ID: 24851035. Study sponsored by Bayer CropScience GmbH, Frankfurt, Germany. Study completed November 21, 2005.

**Disclaimer:** This document may have been revised by USEPA or other review agency subsequent to production by Cambridge Environmental, Inc. personnel.

**Executive Summary:**

A 48-hour acute contact and oral test was conducted with the honeybee, *Apis mellifera*. The contact test had a nominal concentration of 100.0 µg test material/bee and the oral test had a measured concentration of 102.3 µg test material/bee. The treatment groups were compared to a negative and solvent control. In the contact test, there was 2% mortality in the 100.0 µg test material/bee level and no mortality in either control group. No mortality was observed in the oral test and no sublethal effects were observed in either the contact or oral tests. Based on the results of this study, fluopyram would be categorized as practically nontoxic to honeybees on an acute toxicity basis.

**Results Synopsis****Contact Test:**

LD <sub>50</sub> : >100 µg test material/bee	95% C.I.: N/A
NOAEL: 100 µg test material/bee	Probit Slope: N/A
LOAEL: >100 µg test material/bee	

**Oral Test:**

LC <sub>50</sub> : >102.3 µg test material/bee	95% C.I.: N/A
NOAEL: 102.3 µg test material/bee	Probit Slope: N/A
LOAEL: >102.3 µg test material/bee	

**I. REPORTED MATERIALS AND METHODS****A. REPORTED MATERIALS:****1. Test material:**

- AE C656948 (AI: Fluopyram)
- Purity: 95.5%

**2. Test organism:**

Parameters	Reported Information
<b>Species:</b>	<i>Apis mellifera</i>
<b>Age at beginning of test:</b>	4-6 week old females
<b>Supplier:</b>	IBACON
<b>All bees from the same source?</b>	Yes

**B. REPORTED STUDY DESIGN:**

Parameters	Reported Information
<b>Cage size adequate?</b>	stainless steel cages 10 x 8.5 x 5.5 cm.
<b>Lighting:</b>	Constant darkness except during observations
<b>Temperature:</b>	25°C
<b>Relative humidity:</b>	54-70%
<b>Range finding test?</b>	None reported.
<b>Reference toxicant test?</b>	Perfekthion (active ingredient dimethoate; 392.1 g/L)

Parameters	Reported Information
<b>Method of administration:</b>	<u>Contact test:</u> 5 µL applied to ventral thorax <u>Oral test:</u> Diluted with 5% acetone and dispersed in sugar solution
<b>Nominal doses:</b>	<u>Contact test:</u> 0 (negative and solvent controls) and 100 µg test material/bee <u>Oral test:</u> 0 (negative and solvent controls) and 100 µg test material/bee
<b>Controls:</b>	<u>Contact test:</u> negative control- tap water with 1% Adhasit (with anesthetization) Solvent control- acetone with anesthetization <u>Oral test:</u> negative control- tap water and sugar solution Solvent control- acetone and sugar solution
<b>Number of colonies per group:</b>	<u>Contact test:</u> 5 reps, 10 bees per rep <u>Oral test:</u> 5 reps, 10 bees per rep
<b>Solvent:</b>	<u>Contact test:</u> acetone (5%) <u>Oral test:</u> acetone (5%)
<b>Feeding:</b>	Commercial ready-to-use syrup (Apiinvert; 30% Saccharose, 31% Glucose, 39% Fructose) <i>ad libitum</i>
<b>Observations period:</b>	4, 24 and 48 hours after application

Parameters	Reported Information
<b>Quality assurance and GLP compliance statements were included in the report?</b>	<p>Yes, GLP compliant.</p> <p>-The OECD Principles of Good Laboratory Practice (as revised in 1997) ENV/MC/CHEM(98)17</p> <p>-Chemikaliengesetz (‘<i>Chemicals Act</i>’) der Bundesrepublik Deutschland (ChemG), Anhang 1 (‘<i>Annex 1</i>’), 2002</p> <p>-Directive 2004/10/EC of 11 February 2004 (Official Journal No. L. 50/44)</p> <p>Which are consistent with:</p> <p>-U.S. EPA, FIFRA, Title 40 CFR Part 160, Federal Register, 29 November 1983 and subsequent Amendment Federal Register 17 August 1989</p> <p>-Japan MAFF, 11 Nousan, Notification No. 6283, Agricultural Production Bureau, 1 October 1999.</p>
<b>Control performance:</b>	<p><u>Contact test</u>: 100% survival</p> <p><u>Oral test</u>: 100% survival</p>
<b>Raw data included:</b>	Yes
<b>Signs of toxicity (if any) were described?</b>	Yes

## **II. REPORTED RESULTS**

### **A. REPORTED MORTALITY:**

**Mortality - Contact Test**

Dosage µg test material/bee	No. of Bees	Percent Mortality (%)	
		Hour of Study	
		24	48
Test Substance			
Negative Control	50	0	0
Solvent Control	50	0	0
100	50	2	2
Toxic Standard			
0.10	50	10	16
0.15	50	50	74
0.20	50	82	100
0.30	50	94	100

**Mortality - Oral Test**

Dosage µg test material/bee (actual intake)	No. of Bees	Percent Mortality (%)	
		Hour of Study	
		24	48
Test Substance			
Negative Control	50	0	0
Solvent Control	50	0	0
102.3	50	0	0
Toxic Standard (µg ai/bee)			

Dosage µg test material/bee (actual intake)	No. of Bees	Percent Mortality (%)	
		Hour of Study	
		24	48
0.04	50	0	0
0.08	50	2	6
0.15	50	30	42
0.27	50	88	94

**B. REPORTED SUBLETHAL TOXICITY ENDPOINTS:****Contact**

No sub-lethal effects were observed in the controls or 100 µg test material/bee treatment group. The NOAEL and LD<sub>50</sub> values were 100 and >100 µg test material/bee treatment groups, respectively.

**Oral**

No sub-lethal effects were observed in the control or the 102.3 µg test material/bee treatment group, yielding NOAEL and LC<sub>50</sub> values of 102.3 and >102.3 µg test material/bee, respectively.

**C. REPORTED STATISTICS:**

Probit analysis, ToxRat Professional, Version 2.09

**Reported Statistical Results - Contact Test:**

LD<sub>50</sub>: >100 µg test material/bee      95% C.I.: N/A  
 NOAEL: 100 µg test material/bee      Probit Slope: N/A  
 LOAEL: >100 µg test material/bee

**Reported Statistical Results - Oral Test:**

LC<sub>50</sub>: >102.3 µg test material/bee      95% C.I.: N/A  
 NOAEL: 102.3 µg test material/bee      Probit Slope: N/A

LOAEL: >102.3 µg test material/bee

### **III. REVIEWER'S EVALUATION**

**A. DEVIATIONS FROM GUIDELINES:** No deviations were noted.

**B. OTHER STUDY DEFICIENCIES:** None.

**C. VERIFICATION OF STATISTICAL RESULTS:** Lack of mortality precluded statistical analysis. Toxicity values were determined visually.

#### **Results - Contact Test:**

LD<sub>50</sub>: >100 µg test material/bee      95% C.I.: N/A  
NOAEL: 100 µg test material/bee      Probit Slope: N/A  
LOAEL: >100 µg test material/bee

#### **Results - Oral Test:**

LC<sub>50</sub>: >102.3 µg test material/bee      95% C.I.: N/A  
NOAEL: 102.3 µg test material/bee      Probit Slope: N/A  
LOAEL: >102.3 µg test material/bee

**D. ADDITIONAL REVIEWER COMMENTS:** None.

**E. CONCLUSIONS:** This study is/is not scientifically sound and is classified as Acceptable/Supplemental/Unacceptable. After 48 hours, there was 2% and 0% mortality in the contact and oral tests, respectively. In the contact test, the LD<sub>50</sub> was >100 µg test material/bee and the NOAEL was 100 µg test material/bee. In the oral test, The LC<sub>50</sub> was >102.3 µg test material/bee and the NOAEL was 102.3 µg test material/bee. Based on the results of this study, fluopyram would be categorized as practically nontoxic to honeybees on an acute toxicity basis.

### **REFERENCES:**

Abbott W.S. 1925: A method of computing the effectiveness of an insecticide. J. econ.

DP Barcode: D353315

MRID No.: 47372347

Entomol. 18: 265-267.

Chemikaliengesetz der Bundesrepublik Deutschland (ChemG), Anhang 1, in der Fassung der Bekanntmachung vom 20. Juni 2002 (BGBl. I S. 2090).

Commission Directive 96/12/EC, amending Council Directive 87/18/EEC, Official Journal of the European Communities No. L 65: 20-37.

Directive 2004/10/EC of 11 February 2004 amending Council Directive 87/18/EEC, Official Journal of the European Union No L 50: 44-59.

Finney, D.J. 1971: Probit Analysis. 3<sup>rd</sup> Edition, Cambridge University Press, London.

ICPBR (2000) Hazards of pesticides to bees, 7<sup>th</sup> International Symposium of the ICPBR Bee Protection Group, Avignon (France), 07-09 September 1999; Les Colloques d'INRA.

Japan Ministry of Agriculture, Forestry and Fisheries, Notification on the Good Laboratory Practice (GLP) Standards for Agricultural Chemicals, 11 Nousan, Notification No. 6283, Agricultural Production Bureau, 1 October 1999.

OECD Principles of Good Laboratory Practice, adopted by Council on 26<sup>th</sup> November 1997 [C(97)186/Final], Environment Directorate, Organization for Economic Co-operation and Development, ENV/MC/CHEM(98)17, Paris 1998.

OECD Guideline 213 for the Testing of Chemicals on Honeybee, Acute Oral Toxicity Test, adopted on 21<sup>st</sup> September 1998.

OECD Guideline 214 for the Testing of Chemicals on Honeybee, Acute Contact Toxicity Test, adopted on 21<sup>st</sup> September 1998.

Schmitzer, S. Wewer, B., Scazzari, S. (2002): Acute contact to honey bees- 2 answers for 2 questions; Poster Presentation on the 8<sup>th</sup> International Symposium of the ICPBR Bee Protection Group, Bologna (Italy), 04-06 September 2002.

United States Environmental Protection Agency, Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); Good Laboratory Practice Standards, Title 40 Code of Federal Regulations, Part 160, Federal Register, 29 November 1983 and subsequent Amendment Federal Register 17 August 1989.